Title:

State Contracts – Evaluation of Inspectional Performance (FMD#-76)

Sections included in this document

1. Purpose

The purpose of this FMD is to define: (1) procedures for conducting audits of contract inspections, (2) the required frequency of audits, (3) auditor training requirements, and (4) the records required to document the audits. Specific audit procedures and forms, data reporting instructions, and summary report forms of audit findings are included as appendices. This FMD does not modify the procedures for conducting joint audit inspections and joint inspections for contract monitoring and enforcement purposes.

2. Scope

FMD-76 addresses the oversight of contract inspections in the following program areas:

- Food
- Feed establishment (includes GMP and BSE only inspections)
- Egg, tissue residue, medical device, and other inspection programs[1]

This FMD does not address the training requirements and procedures for oversight of States performing inspections of mammography facilities certified by FDA under the Mammography Quality Standards Act of 1992 (MQSA). Those requirements are contained in the MQSA contractual agreements with the States and the FMD-144.

This FMD does not contain procedures for reviewing the quality of State documents. Districts are encouraged to conduct a quality assurance review of State documents as part of their quality assurance program.

3. Guidelines

FMD-76 is the overarching document for oversight of the State contract audit program.

4. Background

[1] "other inspection programs" are inspection programs not specifically named in this FMD.

The original FMD established procedures for joint inspections and independent audit inspections for the food, medicated feed (currently feed establishments), and interstate travel programs. In 1977, a revision expanded the audits, maintained the requirement for joint inspections, and added references to the diagnostic x-ray program. In 1982, a revision combined the general procedures for all current programs into one document. Guidance for auditing food sanitation and medicated feed contract inspections, and the procedures for auditing States performing inspections of mammography facilities certified by FDA under the Mammography Quality Standards Act of 1992 (MQSA) were added in 1999.

In June 2000, the Department of Health and Human Services, Office of Inspector General (OIG) published the results of its evaluation of FDA's oversight of food firm inspections conducted by States through contracts. The report recommended that FDA take steps to address shortcomings in its system of oversight. In 2006, this FMD was revised to incorporate the OIG's recommendations and to improve the oversight of food, feed establishment, and other inspections done under contract by the States. The procedures for auditing States performing MQSA inspections were removed since they are contained in the State contracts and the FMD-144.

This FMD was updated in 2012 to strengthen the processes for ensuring the audit rates are met and identifying and correcting systemic problems identified during the audits. The revision expanded the oversight of egg contract inspections and added procedures and computer automated forms to improve reporting and tracking of the required number of audits throughout the year.

5. Procedures/Responsibilities

5.1 Responsibilities

A. The Associate Commissioner of Regulatory Affairs (ACRA)
   1. Ensures the Regional Food and Drug Directors (RFDDs) comply with the requirements of FMD-76.
   2. Initiates actions to correct regional and National deficiencies.

B. FDA's Office of Regulatory Affairs, Office of Partnerships (OP)
   1. Primary oversight of the State contract inspection and audit program.

C. Regional Food and Drug Directors (RFDDs)
   1. Ensures the District Directors comply with the requirements of FMD-76.

D. District Directors (DDs)
   1. Ensure the required numbers of audits are completed.
   2. Ensures documented program and performance deficiencies are corrected.

3. Ensures adequate staff is assigned to meet the responsibilities of the Audit Program.

E. FDA Auditor
1. Conduct audits of State inspectors performing contract inspections.
2. Train and verify the performance of State Auditors.
3. Submit audit reports to the district.

F. State Auditor (Phase II and III only)
1. Conduct audits of State inspectors performing contract inspections.
2. Train and verify the performance of State Auditors.
3. Submit audit reports to the District for review through the State agency.

G. State Contract Liaisons/Monitors, or designee
1. Manage Contract Inspection Audit Program at the district level.
2. Inform District management of contract audit performance.
3. Work with management at District and State agency to:
   a. Assign audits to FDA employees.
   b. Ensure the required numbers of audits are completed and that identified inspectors are audited
   c. Document and ensure correction of individual and program performance deficiencies
   d. Ensure required documentation, including audit reports, are completed, maintained, and distributed, as needed.

5.2 Overview

FDA must audit contract inspections to ensure the quality of inspections purchased through contracts with States is adequate and complies with the contract requirements. The Contract Inspection Audit Program (hereafter known as the Audit Program) is a standardized system of formal audits conducted by qualified FDA and State auditors at a minimum frequency or audit rate. Implementation of the Audit Program is described here.

There are three phases of auditing.
1. **Phase I:** the District is responsible for conducting the minimum number of contract audits.
2. **Phase II:** the District and State agency share responsibility for conducting the minimum number of contract audits to meet the audit rate.
3. **Phase III:** the State agency assumes full responsibility for conducting the minimum number of contract audits to meet the audit rate.

NOTE: Phases II and III apply to the food contracts only. Appendix H (State Implementation Agreement and Year End Evaluation) must be submitted with the food

contract proposal. Section 5.12 provides guidance for implementing Phases II and III of the Audit Program.

5.3 Auditor Qualifications

Contract audits are conducted by FDA and State auditors who have completed the required training courses relevant to the inspection programs listed in this section and any additional training courses listed in the related contract. The auditors must have experience in conducting inspections in the program area and should have an understanding of the relevant FDA compliance program and regulations. Additional qualifications for State Auditors are listed in Section 5.12.

5.3.1 Food Contract Auditor Training Requirements

1. FD320 - FDA State Food Contract Audit Course

2. Contract inspections that require a State inspector to complete specific training courses shall be audited by FDA and State auditors who have completed the same course requirements listed here.

   a. Low-Acid Canned Food and Acidified Food
      - FD202 – Conducting Acidified Food Inspections
      - FD304 (formerly FD203) – LowAcid Canned Food Inspections

   b. Seafood HACCP
      - FD249 – Conducting Seafood Inspections

   c. Juice HACCP
      - FD219 – Juice HACCP and Conducting Juice Inspections

5.3.2 Feed Establishment Contract Auditor Training Requirements

1. VM212 - FDA BSE/Feed Establishment Contract Audit Course

2. Contract inspections that require a State inspector to complete specific training courses shall be audited by FDA auditors who have completed the same course requirements listed here.

   a. BSE01- Bovine Spongiform Encephalopathy (BSE) (FDA web-based course)
   b. BSE02 - BSE Inspectional Approach (FDA web-based course)
   c. VM206 - Medicated Feeds Inspection (recommended)
   d. VM213 – BSE Inspection Training (recommended)

3. Knowledge of Compliance Programs and forms, including completing the REPORT OF INSPECTION FOR COMPLIANCE WITH 21 CFR §589.2000 and §589.2001.

5.4 Audit Rates

5.4.1 Minimum Audit Rates

The minimum audit rates to be accomplished each contract year by inspection program are shown in Table 1. All food and feed inspectors must be audited a minimum of twice in a 36 month period. Districts must provide the following information to OP prior to the start of the contract period of performance, via email to ContractAudits@fda.hhs.gov, or complete Appendix H. For states in the audit program, Appendix H should be submitted with the contract proposal. State agencies must provide:

- Contract type (food or feed)
- Number of inspections to be performed
- Number of inspectors performing contract inspections
- Number of audits to be performed during the contract year
- Names of inspectors to be audited during the contract year

In split-district States, the required number of audits is prorated based on the number of firms covered by the State in each District's territory.

Table 1: Audit Rate for Contract Inspection Programs

Inspection program	Minimum audit rate
Food[2]	2 audits per inspector every 36 months
Feed establishment[3]	2audits per inspector every 36 months
Egg, tissue residue, medical device, and other inspection programs	One joint audit inspection of each inspection program

OP emails a status reminder to the State Contract Liaisons/Monitors at the end of the second quarter of the contract period of performance if less than 25 percent of

[2] includes low-acid canned foods and acidified foods, seafood HACCP, and juice HACCP inspections, where appropriate.
[3] includes BSE only inspections and inspections at licensed and non-licensed feed mill inspections.

the required audits of a State's food or feed contract inspections have been completed.

5.4.2 Audit Selection

District and the State agency managers develop an audit schedule when assigning the firms to be inspected under contract by the State agency. Firm selection should be based on the inspection priorities listed in the "Statement of Work" section of the contract and the contractual obligation of the contractor including, for food contracts only, the State's implementation of the contract audit program.

The types of contract inspections conducted by an inspector must be considered when scheduling an audit. If a State inspector conducts contract inspections in more than one program area, the most complex inspections (i.e. seafood HACCP, juice HACCP, LACF, medicated feed, BSE, etc.) should be audited and the State or District must rotate the audits to ensure the State inspector is audited conducting a contract inspection in all applicable program areas.

A training or verification audit is counted as one audit, because a single contract audit is being performed during a training or verification audit of a State auditor. Districts may schedule joint inspections as needed for training purposes. District approved joint inspections count toward audit rate.

5.4.3 Audit Rate Reduction

In limited circumstances, the audit rate may be reduced. OP will consider the number and type of contract inspections, the number of State inspectors conducting the contract inspections, and previous individual and program performance when evaluating audit rate reduction requests. The OP Director will have final discretion in granting a reduction in Audit Rate. If an audit reduction is not approved OP will provide an explanation and the District will have an opportunity to provide additional information.
The State and District understand that the audit reduction is valid for the period of performance specified in this agreement. The audit reduction will be reevaluated if any of the following conditions occur: (1) the State increases the number of inspectors conducting contract inspections; (2) an inspector receives an overall rating of needs improvement; and/ or (3) there are significant modifications to the contract (e.g. adding specialized inspections or increasing number of inspections). It is the responsibility of the District and State to report any changes to the information provided on the form. If the information provided on the form changes, the State shall notify the District within 10 working days. The District is responsible for reporting the changes to Office of Partnerships (OP) within 10 working days. A new Request for Audit Reduction form may be needed.

Audit reductions will not be given when a District or State agency fails to conduct the required audits.
The District must submit Appendix I, Request for Audit Reduction, to OP via email to ContractAudits@fda.hhs.gov, during the first quarter of the contract period of performance. Requests may be submitted later if conditions change during the contract period of performance. Submit a separate form for each program if an audit reduction is being requested in both feed and food. OP will provide a response within 20 business days of receiving the request. The audit rate reduction is valid for the specified period of performance in Appendix I and will be canceled if conditions change.

5.5 Procedures

This section describes the references, rate of audit, performance documentation, performance factors, and timeframes for submitting performance documents for all contract inspection programs.

5.5.1 Food

References

Food Contract: Statement of Work (SOW)

Appendix A	Instructions for Evaluating Contract Inspections
Appendix B	Contract Audit Form (Form FDA 3610)
Appendix B.1	Guidance for Completing the Contract Audit Form (Form FDA 3610)
Appendix B.2	Instructions for Reporting Food Contract Audits in FACTS and eSAF
Appendix D	Guidance for Conducting Joint Audit Inspections, Verification Audits for State Auditors, and Joint Inspections

Rate of Audit

Every inspector must be audited a minimum of twice in 36 months.

Performance Documentation

For contract audits

Appendix B — Contract Audit Form (Form FDA 3610) is used to evaluate the State inspector's performance.

For 36-month verification audits of State auditors

The FDA or State auditor will prepare a memorandum to document the State auditor's performance.

Performance Factors

For contract audits

Performance factors are found in Appendix B.

For 36-month verification audits of State auditors
Follow guidance in Appendix D.

Timeframe for Submitting Performance Documentation

FDA will send a copy of the audit form or the memorandum to the State agency no later than 20 business days after the audit is completed.

When the State agency conducts the audit, it will send the original audit form or memorandum for the verification audit to the District no later than 20 business days after the audit is completed.

If a contract audit is rated as "needs improvement," the District or State agency should notify the other party no later than 10 business days after the audit is completed.

If a verification audit is unacceptable, the District or the State agency should notify the other party no later than 10 business days after the audit is completed.

5.5.2 Feed Establishment

References

Feed establishment contract: Statement of Work (SOW)

Appendix A	Instructions for Evaluating Contract Inspections
Appendix C	BSE/ Feed Establishment Audit Form
Appendix C.1	Guidance for Completing the BSE/ Feed Establishment Audit Form
Appendix C.2	Instructions for Reporting CVM Contract Audits in FACTS

Rate of Audit

Every inspector must be audited a minimum of twice in 36 months.

Performance Documentation

Appendix C BSE/ Feed Establishment Audit Form

Performance Factors

Performance factors are found in Appendix C.

Timeframe for Submitting Performance Documentation

FDA will send a copy of the audit form to the State agency no later than 20 business days after the audit is completed.

If an audit is rated as "needs improvement," the District should notify the State agency no later than 10 business days after the audit is completed.

5.5.3 Egg, Tissue Residue, Medical Device, and Other Inspection Programs

References	Refer to Relevant Contract: Statement of Work (SOW) Appendix A Instructions for Evaluating Contract Inspections Appendix D Guidance for Conducting Joint Audit Inspections, Joint Inspections, and Verification Audits for State Auditors
Rate of Audit	One joint audit inspection of each inspection program every contract year.
Performance Documentation	For joint audit inspections The FDA auditor will prepare a memorandum to document the State inspector's performance.
Performance Factors	For joint audit inspections Performance factors are found in Appendix D.
Timeframe for Submitting Performance Documentation	FDA will send a copy of the memorandum to the State agency no later than 20 business days after the audit is completed. If the joint audit inspection is unacceptable, the District should notify the State agency no later than 10 business days after the audit is completed.

5.6 Reporting Audit Findings

The District reports the audit findings for each quarter. All audit results must be reported, even when more than the required numbers are performed.

5.6.1 Food and Feed contracts

The District completes Workbooks E and F (Appendices E and F) and emails them to the State agency and the OP audit mailbox ContractAudits@fda.hhs.gov no later than 20 business days after the end of each quarter of the contract period of performance. Workbooks E and F are used: (1) to calculate an overall rating for the contract period of performance and (2) to evaluate the audit ratings for a single performance factor. The District, State agency, and OP use the rating and evaluation to identify specific aspects of the State's inspection program that require improvement.

5.6.2 Egg, tissue residue, medical device, and other inspection programs

Appendix G, Audit Summary for Other Inspection Programs, is emailed to the OP audit mailbox ContractAudits@fda.hhs.gov no later than 20 business days after the end of the contract period of performance.

5.7 Audit Rate Deficiencies

The District and State agency must take action when the minimum audit rate is not met. A memorandum approved by the DD and RFDD must be emailed to the Director, Contracts and Grants, OP (CGS) no later than 20 business days after the end of the contract period of performance. The memorandum should have the following information:

- the number of inspections awarded in the contract and the number of inspections for each type of inspection
- the number of audits completed for each type of inspection
- the number of audits not completed
- detailed reasons for not completing the required number of audits
- detailed recommendations for solving issues that caused the required number of audits not to be met
- detailed proposal for meeting the required number of audits for the next contract period of performance

In Phase I, the District prepares the memorandum.

In Phase II, the District and State agency work together to prepare the memorandum. The District also documents how to increase oversight of the program and, if necessary, implement action to assume increased responsibility for completing the audits. The Director, OP reviews the memorandum and discusses the need to adjust the State agency's implementation phase with the DD and the Director of the State food program.

In Phase III, the Director of the State food program prepares the memorandum and sends it to the DD. The DD forwards it to the RFDD with a cover letter having the following content:

- support of the memorandum submitted by the State food program
- summary of discussions held between District and State food program to prevent program deficiencies from reoccurring
- district's proposal for increasing oversight of the audit program to ensure the required number of audits are met in the next contract period of performance

5.8 Performance Deficiencies

5.8.1 Individual Performance Deficiencies

When there is an individual performance deficiency, the District or State agency notifies the other party no later than 10 business days after the audit is completed.

An individual performance deficiency occurs when:

- a contract audit is rated "needs improvement"
- performance deficiencies are found during a verification audit of a State auditor conducted by the District (applies to food contracts only)
- a joint audit inspection of an inspector conducting an egg, tissue residue, medical device, or other inspections done under contract is unacceptable

5.8.2 Program Performance Deficiencies

When there is a program performance deficiency, the District or State agency notifies the other party no later than 10 business days after the end of the contract period of performance.

A program performance deficiency occurs when:

- a single performance factor rated as "needs improvement" occurs in four or more audits. If fewer than four audits are conducted, a performance deficiency may be considered for a single performance factor rated as "needs improvement" at the discretion of the District and the State agency
- the overall audit performance rating is below 90 percent

5.8.3 Documenting and Correcting Performance Deficiencies

The District or State agency follows these steps to address individual or program performance deficiencies:

- provide a copy of the performance documents (audit form, memorandum, or yearend summaries) to the State agency
- develop a plan to correct the deficiencies. The plan must address (1) the possible causes for the individual or program performance deficiency and (2) the corrective actions that will improve performance
- complete the Appendix J, Corrective Action Plan for Program and Individual Performance Deficiencies and submit to OP upon completion of the corrective actions.

The District or State agency follows these additional steps to address individual performance deficiencies identified during audits:

- the District and State agency discuss the deficiencies identified during the audit. The State inspector or State auditor discontinues conducting or auditing that type of inspection, respectively, until remedial training is completed. The State may be required to absorb the cost of the training.
- State inspectors receiving an overall rating of "needs improvement" must complete remedial training in deficient areas. The District and State agency managers agree on the remedial training needed to allow the State inspector or State auditor to resume conducting or auditing contract inspections, respectively. The remedial training should directly address the deficiencies noted during the audit.
- After remedial training is completed, the State agency conducts an internal audit of the State inspector or State auditor while conducting or auditing a non-contract inspection, respectively. The internal audit should evaluate the effectiveness of the remedial training.
- The District audits the State inspector or State auditor while conducting or auditing a contract inspection, respectively, once remedial training and the internal audit has been completed.

5.9 Process for Contract Modifications for Program and Performance Deficiencies

The District immediately notifies the Contracting Officer Representative (COR), listed in the SOW, of any individual or program performance deficiencies that may affect a contractual requirement. The District provides the COR with additional notification of all follow-up actions and copies of any written correspondence to the State agency.

If the District proposes a change to the contract, the DD emails a recommendation to change the contract to the RFDD, who in turn emails the memorandum to the Director, CGS no later than 10 business days after the end of the contract period of performance.

The recommendation must contain the following information:

- documentation of the problem. Attach copies of pertinent State inspection reports and FDA audit reports
- a description of the steps taken by the State agency and the District to correct the problem
- copies of correspondence such as emails between the District and State agency documenting efforts to address and correct the problem
- an assessment by the District of the cause of the problem and suggested changes to the contract

The Director, CGS and the COR review the District's proposal to determine if the recommended action is appropriate and complies with contracting regulations and procedures. The Director, CGS discusses with the District any potential action to be taken. OP requests the Office of Acquisitions and Grant Services (OAGS) send an official notification of any action to the contractor. Any actions pursued under this section are done in accordance with the guidance provided in the SOW regarding alteration of the contract and payment for work conducted under the contract.

5.10 Dispute Resolution

The District and the State agency must make every effort to resolve disputes about audit findings and overall audit ratings. If, however, the District and State agency are unable to resolve a dispute, both parties send a written summary of the situation and a proposed resolution to the Director, OP. All related documents, including the FDA audit reports and State inspection reports, shall be included. The Director, OP reviews the reports and works with the District and the State agency to arrive at a resolution. If the State agency fails to respond, the disposition of the contract may be effected.

5.11 Reporting National Audit Findings

The OP conducts a comprehensive review and analysis of the audit data and the documents associated with the audits for all inspection programs covered in this FMD. If a national trend is identified, OP submits a corrective action through the Quality Management System. OP prepares a written report that summarizes the audit findings and accomplishments and describes program and performance deficiencies and corrective actions. The Director, OP will provide the written report to the Associate Commissioner for Regulatory Affairs (ACRA), and other designated managers.

After the audit completion data is reviewed by the ACRA, it will be posted on www.FDA.gov.

5.12 State Implementation of the Audit Program: Phases II and III

Section 5.12 ONLY applies to food contracts.

5.12.1 Contract

Full implementation of the Audit Program occurs when the State agency assumes responsibility for auditing their food contract inspections. This process begins in Phase II and is completed in Phase III. Phases II and III of the Audit Program are offered to the State agency as an elective under the Food Contract SOW. If the State agency bids on the audit option, the Appendix H, State Implementation Agreement and Yearend Evaluation, is signed by the District and the State agency and must be submitted with the State's contract proposal.

For states in Phase I the District will complete Appendix H, is signed only by the District, and submitted to OP at Contractaudits@fda.hhs.gov.

At the end of the contract performance period, the agreement is updated by the District to include a yearend evaluation and a summation of the number of audits completed. The updated agreement is emailed to the State agency and to the OP audit mailbox ContractAudits@fda.hhs.gov no later than 20 business days after the end of the contract period of performance.

5.12.2 Training and Verification

The District and State agency develop a plan to accomplish the training and verification audits for those State inspectors who have completed the training requirements in Section 5.3.1 and the SOW. If requested by the District, the State agency will provide records to verify that State auditors have completed the prerequisite training requirements.

In addition, the State auditor must complete one training audit and one verification audit for each type of inspection that the auditor will be responsible for auditing. For example, to conduct audits for GMP and seafood HACCP (SFD), the State auditor must complete at least one training and one verification audit for GMP and one training and one verification audit for SFD.

FDA auditors train and verify the performance of State auditor trainees. States with one qualified auditor may conduct the training and verification audits for other State auditor trainees. States with two qualified State auditors may conduct verification audits of State auditors following the Phase III audit procedures (See 5.12.3). The contract audits completed during the training and verification audits will be counted towards the audit obligation.

One auditor should train only one State auditor trainee during a contract inspection. The State supervisor or additional State inspectors are not permitted to accompany the auditor during a training or verification audit.

A. During the training audit, the State auditor trainee observes the FDA or State auditor conducting a contract inspection audit. The auditor, not the trainee, completes Form FDA 3610.

B. During the verification audit, the FDA or State auditor observes the State auditor trainee conducting a contract audit. The State auditor trainee completes Form FDA 3610. The original audit forms are submitted to the District contact person no later than 20 business days after the audit. The auditor follows the guidelines in Appendix D to document the State auditor trainee's performance during the verification audit. A copy of the

memorandum is sent to the State agency when FDA conducts the audit, and vice versa.

Only the State inspector, not the State auditor, will report his/her time in eSAF. The number of hours will be reported as an audit, not an inspection. At the time data is entered into eSAF, the State data entry user will change the *Inspection Type* field on the Add/Update Inspection Operation screen from "State" to "Audit."

5.12.3 Phase III

Phase III occurs when the State agency assumes full responsibility of auditing their food contract inspections. The State agency must have a quality assurance program (QAP) that requires correcting performance deficiencies found during an inspection or an audit. The QAP should describe the remedial training process and an internal audit of an auditor who fails to recognize: (1) deficient performance by an auditor or inspector or (2) inspector's performance that should be rated as "needs improvement", as discussed in Section 5.8 of this FMD.

All State auditors are listed in Appendix H, Section V. The State agency must audit its own auditors every 36 months considering the inspection priorities listed in the food contract SOW and the inspections performed under contract. To meet this requirement, the State agency must have a minimum of two qualified State auditors. If during the contract year the State agency is unable to retain a qualified auditor for contracted specialized inspections or a minimum of two auditors, it stays in Phase III for the remainder of the contract year. The State agency is moved to Phase II the following contract year and remains in Phase II until they have a minimum of two qualified auditors or a qualified auditor for contracted specialized inspections. If the change in implementation was due to the loss of a qualified auditor for contracted specialized inspections, the State agency may renegotiate their contract to exclude the specialized inspections.

FDA also conducts a minimum of one audit of each State auditor every 36 months. The FDA auditor evaluates the State auditor's performance over a representative sample of audits of contract inspections, giving priority to auditing those State auditors trained and verified by the State agency.

Both audits by the State and FDA follow the procedures in Sections 5.5.1 and 5.12.2 of the FMD-76 for conducting and documenting a verification audit.

5.13 Quality Assurance

Within the first quarter of the following contract year, the Quality System Manager (QSM), or person designated by the DD, conducts an internal audit of the previous contract year to ensure the District followed the requirements in this FMD and

applicable SOP. The internal audit findings will be provided to the DD. All nonconformances must be documented and addressed according to QMS procedures.

6. References/ Supporting Documents

All references and supporting documents are included in Section 5, Procedure/ Responsibilities, Section 9, Attachments, and/ or the contract SOW. Additional resources may be found online at www.fda.gov. Users are responsible for ensuring that they are using the most up-to-date version of the referenced documents.

7. Definitions/ Glossary

The types of audits relevant to the oversight of contract inspections are defined here.

1. Audit Performance Rating is the comprehensive assessment of all audits conducted in a contract program during a single period of performance. The Performance rating is calculated based on the rating of all individual performance factors as follows: Total Acceptable/ (Total Acceptable + Total Needs Improvement) * 100. The Audit Performance Rating is expressed as a percentage. The Audit Performance Rating must be greater than or equal to 90percent.

2. Contract audit is an evaluation of a contract inspection in which a qualified auditor accompanies a State inspector to document the inspector's performance. FDA investigators or State inspectors are qualified to conduct a contract audit after all the requirements for the specific inspection program listed in Sections 5.3 have been successfully completed.

3. Joint audit inspection is an audit conducted by an FDA investigator accompanying a State inspector and observing his/her performance. A joint audit inspection is used to assess the quality of contract inspections for egg, tissue residue, medical device, and other industries that are not covered by an FDA audit course. Appendix D provides guidelines for conducting and reporting joint audit inspections.

4. Joint inspection is an inspection conducted jointly by District and State personnel for training. Joint inspections may be counted towards the required number of audits when used to train state inspectors. Training may be necessary when a new contract is negotiated, new industries are added to an existing contract, or remedial training is needed. If authorized in the contract, the State agency may count the joint inspection as a contract inspection. Appendix D provides additional guidelines for conducting and reporting joint inspections

5. Overall Audit Rating is the comprehensive assessment for an individual audit (see Appendices B and C). If three or less items are marked "needs improvement," the overall rating is "acceptable." If four or more items are marked "needs improvement," the overall rating is "needs improvement."

6. Training audit is an audit in which a State auditor trainee accompanies an FDA or State auditor and the State inspector during a contract inspection. Its purpose is to teach the State auditor trainee how to conduct an audit by observing an audit of a State inspector. The State auditor trainee must also meet the auditor qualifications in Sections 5.3, 5.12, and in the food inspection contract SOW.

7. Verification audit is an audit conducted by an FDA or State auditor to verify the ability of the State auditor trainee or State auditor to audit the inspection performance of a State inspector conducting a contract inspection. Appendix D provides guidance for conducting and reporting verification audits.

8. Records

Records must be maintained and distributed in accordance with Section 5 (Procedure/ Responsibilities) and other applicable requirements.

9. Attachments

Appendix A	Instructions for Evaluating Contract Inspections
Appendix B	Contract Audit Form (Form FDA 3610)
Appendix B.1	Guidance for Completing the Contract Audit Form
Appendix B.2	Instructions for Reporting Food Contract Audits in FACTS and eSAF
Appendix C	BSE/Feed Establishment Audit Form
Appendix C.1	Guidance for Completing the BSE/Feed Establishment Audit Form
Appendix C.2	Instructions for Reporting CVM Contract Audits in FACTS
Appendix D	Guidance for Conducting Joint Audit Inspections, Verification Audits for State Auditors, and Joint Inspections
Appendix E	Summary of Contract Audit Findings: Food Inspections
Workbook E	Food Audits
Appendix F	Summary of Contract Audit Findings: Feed Establishment Inspections
Workbook F	Feed Audits
Appendix G	Audit Summary for Other Inspection Programs and Instructions

Workbook G Other Inspection Program Audits

Appendix H State Implementation Agreement and Yearend Evaluation

Appendix I Request for Audit Reduction Form and Instructions

Appendix J Corrective Action Plan for Program and Performance Factors

Document History/Change History

Version #	Status* (D,I, R, C)	Date	Author Name and Title	Approving Official Name and Title
1.0	R	1/10/14	BEVERLY KENT, OP OIG WORKING GROUP	BARBARA CASSENS, ACTING DIRECTOR OP
2.0	R	4/30/15	CATHY HOSMAN, OP FMD 76 WORKING GROUP	BARBARA CASSENS, ACTING DIRECTOR OP

- D: Draft, I: Initial, R: Revision, C: Cancel

1.0 Previous versions of this document exist and are archived, however version numbering was not included. This is the first version in the new format.

2.0 Removed responsibility for Districts to develop individual procedures for implementing this FMD. Added recommendation in 5.3.2 for feed auditors to have the VM213 BSE Inspection Training. 5.4.1 - Revised audit rate to include minimum of two audits per inspector every 36 months. 5.4.2 - Added clarification that audits should be conducted on the most complex program. . 5.8.3 – Added requirement for submission of corrective action plans to OP. 5.11 – Added requirement to initiate a corrective action in QMS for national performance deficiency trends.